REMARKS/ARGUMENTS

Claim Amendments

By the present amendment, claims 10 and 12 have been amended to delete reference to "endoglycan" consistent with the restriction requirement. Claim 12 has also been amended to include detecting "a cancer at risk of metastasis". Support for this amendment can be found on page 43 under the section entitled "High Podocalyxin Expression is an Independent Marker of Poor Outcome". Claims 34, 35 and 37 have been amended to add a dependency on claim 10. Claims 1, 2 and 5-9 have been cancelled. New claim 39 has been added and finds support throughout the specification including at page 14, lines 19-23. New claims 40-45 have been added and find support throughout the specification including page 43, lines 15-17. The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. Applicant reserves the right to pursue any of the deleted subject matter in a further divisional, continuation or continuation-in-part application. No new matter has been entered by the present amendment and its entry is respectfully requested.

The office action dated January 22, 2009 has been carefully considered. It is believed that the amended claims and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

Specification

The Examiner objected to Figure 5 as containing a sequence that is not identified by a SEQ ID NO:. Applicant respectfully disagrees. Applicant points the Examiner to the Response to Notification of Missing Requirements filed on March 13, 2007, where the Applicant amended the brief description of drawings on page 9, line 29 to refer to SEQ ID NOs:1-9.

The Examiner objected to the disclosure on page 43, line 10 as containing an embedded hyperlink and/or other form of browser-executable code. Applicant has amended page 43, line 10 to remove the embedded hyperlink.

The Examiner objected to the disclosure as the listings are for Figure 8(A) and Figure 8(B) but there are no corresponding drawings. Applicant has amended Figure 8 to specify Figure 8(A) and Figure 8(B) to correspond with the description.

In view of the above, Applicant respectfully requests that the objections to the specification be withdrawn.

35 U.S.C. 102

The Examiner rejected claims 1, 2, 6-10, 12 and 35-38 under 35 U.S.C. 102(e) as being anticipated by Xu et al. (US Patent No. 6,613,515, issued Sept. 2, 2003, filed Aug. 15, 2000). According to the Examiner, Xu et al. discloses that podocalyxin is overexpressed in ovarian carcinoma tissues (Table VI) compared to normal ovarian tissue and that the mRNA and protein may be detected. Applicant respectfully disagrees for the reasons that follow.

Claims 1, 2 and 6-9 have been cancelled rendering the Examiner's rejection to those claims moot. Claim 10 is directed to a method of monitoring cancer progression comprising detection of podocalyxin and claim 12 is directed to the determination of whether a cancer is metastatic comprising detection of podocalyxin. The expression of podocalyxin in Xu et al. merely shows that podocalyxin is differentially expressed in a metastatic ovarian tumor subtraction library. In contrast, the present application demonstrates that high podocalyxin expression is an independent marker of poor outcome in breast cancer through multi-variant Cox regression analysis. Further the present inventors have shown that podocalyxin expression leads to disruption of tight junctions and delamination of MCF-7 breast tumor cells, a process that further exemplifies the cancerous effects of podocalyxin. There is no disclosure or suggestion in Xu et al. that increased expression of podocalyxin in ovarian tumors is indicative of poor outcome or metastasis, and thus, Applicant respectfully submits that Xu et al. does not anticipate the present claims.

The Examiner rejected claims 1, 2, 5-10, 12 and 34-38 under 35 U.S.C. 102(e) as being anticipated by Erlander et al. (US Patent Application No: 2004/0002067, published Jan 1, 2004, filed December 21, 2001). Applicant respectfully disagrees for the following reasons.

Claims 1, 2 and 6-9 have been cancelled rendering the Examiner's rejection to those claims moot. Claim 10 is directed to a method of monitoring cancer progression comprising detection of podocalyxin and claim 12 is directed to the determination of whether a cancer is metastatic comprising detection of podocalyxin. Table VI of Erlander et al. discloses more than 350 sequences of which podocalyxin is one sequence. The Examples of Erlander et al. discriminate between normal/atypical hyperplasia (i.e., non-cancer) and ductal carcinoma in situ and IDC. Thus, there is no differentiation between high and low risk cancer, only between non-cancer and cancer.

In contrast, as stated above, the present application demonstrates that high podocalyxin expression is an independent marker of poor outcome in breast cancer through multi-variant Cox regression analysis. Further the present inventors have shown that podocalyxin expression leads to disruption of tight junctions and delamination of MCF-7 breast tumor cells, a process that further exemplifies the cancerous effects of podocalyxin. There is no disclosure or suggestion in Erlander et al. that increased expression of podocalyxin *per se* in breast cancer is indicative of poor outcome or

metastasis. Thus, Applicant respectfully submits that the present claims are novel over Erlander et al.

In view of the above, Applicant respectfully requests that the rejection to the claims under 35 U.S.C. 102(e) be withdrawn.

The Commissioner is hereby authorized to charge any fee (including any claim fee) which may be required to our Deposit Account No. 02-2095.

In view of the foregoing comments and amendments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater detail, he is kindly requested to contact the undersigned by telephone at (416) 957-1678 at his convenience.

Respectfully submitted,

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By _____

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Encl.